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IN THE WHITE STATES PATENT AND TRADEMARK OFFICE

Applicants : Susumu MUTO et al.

Group Art Unit: Not Yet Assigned

Appl. No. : 10/516,294

(U.S. National Stage of PCT/JP03/07119)

I.A. Filed : June 5, 2003

Examiner: Not Yet Assigned

For : NF-KB ACTIVATION INHIBITORS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop AMENDMENT
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, Applicants hereby bring the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited and discussed in the specification, and the International Search Report issued in connection with International Patent Application No. PCT/JP03/07119, which published as WO 03/103654 A1 on December 18, 2003, of which the present application is the U.S. National Stage Application. Copies of the International Search Report (in English and Japanese), Written Opinion (in Japanese), and International Preliminary Examination Report (in Japanese) were enclosed with the papers when entering the National Stage on December 8, 2004. Applicants enclose herewith a copy of the International Preliminary Examination Report in English. The following is a list of the documents cited in the above-noted documents:

CLARK, et al., "Nucleic Acids Research," 1986, Vol. 14, No. 20, page 7897-7914. Applicants note that this document is cited on page 1 of the specification of the present application;

NEDOSPASOV, et al., "Cold Spring Harbor Symposia on Quantitative Biology,"1986, Vol. 51, No.1, page 611-624. Applicants note that this document is cited on page 1 of the specification of the present application;

VERMA, et al., "Genes and Development" 1995, Vol. 9 No. 22, page 2723-2735. Applicants note that this document is cited on page 1 of the specification of the present application;

DiDONATO, et al., "Nature," 1997, Vol. 388, page 548-554. Applicants note that this document is cited on page 1 of the specification of the present application;

RÉGNIER, et al., "Cell," 1997, Vol. 90, No.2, page 373-383. Applicants note that this document is cited on page 1 of the specification of the present application;

WORONICZ, et al., "Science," 1997, Vol. 278, page 866-869. Applicants note that this document is cited on page 2 of the specification of the present application;

ZANDI, et al., "Cell," 1997, Vol. 91, No.2, page 243-252. Applicants note that this document is cited on pages 1-2 of the specification of the present application;

KOPP, et al., "Science," 1994, Vol. 265, page 956-959. Applicants note that this document is cited on page 2 of the specification of the present application;

YIN, et al., "Nature," 1998, Vol. 396, page 77-80. Applicants note that this document is cited on page 2 of the specification of the present application;

SCHEINMAN, et al., "Science," 1995, Vol. 270, page 283-286. Applicants note that this document is cited on page 2 of the specification of the present application;

MANNA, et al., "The Journal of Immunology," 1999, Vol.162, No. 4, page 2095-2102. Applicants note that this document is cited on page 2 of the specification of the present application;

SULLIVAN, et al., "The Journal of Medicinal Chemistry," 1998, Vol. 41, No. 4, page 413-419. Applicants note that this document is cited on page 2 of the specification of the present application;

MATSUMOTO, et al., "Bioorganic and Medicinal Chemistry Letters," 2000, Vol. 10, No. 9, page 865-869. Applicants note that this document is cited on page 2 of the specification of the present application;

WO 97/09315, together with an English language Abstract of family member Japanese Patent Publication (KOHYO) HEI 11-0512399 and U.S. family members 5,852,028, 5,811,428 and U.S. 5,935,966. Applicants note that the Japanese Patent Publication is cited on page 2 of the specification of the present application;

Japanese Laid-open Patent Publication No. HEI 9-227561, together with an English language Abstract of the same. Applicants note that this document is cited on page 2 of the specification of the present application;

Japanese Laid-open Patent Publication No. HEI 10-87491, together with an English language Abstract of the same. Applicants note that this document is cited on page 2 of the specification of the present application;

European Patent Publication No. EP 1 018 514, together with family member WO 00/05234, together with an English language Abstract of the same and U.S. family member U.S. 6,734,180. Applicants note that this document is cited on page 2 of the specification of the present application:

WO 99/65449. Applicants note that the International Patent Publication is cited on pages 2, 207, 208, 210, and 211 of the specification of the present application;

European Patent Publication No. EP 1 314 712, together with family member WO 02/076918 and U.S. Patent Publication No. 2004/122244 A1. Applicants note that the International Patent Publication is cited on page 2 of the specification of the present application;

Japanese Laid-open Patent Publication No. HEI 10-45738, together with an English language Abstract of the same. Applicants note that this document is cited on page 2 of the specification of the present application;

European Patent Publication No. EP 1 344 525, together with family member WO 02/051397 and U.S. family member 2004/048891 A1. Applicants note that the International Patent Publication is cited on pages 2-3 of the specification of the present application;

U.S. Patent No. 6,117,859, Applicants note that this document is cited on page 3 of the specification of the present application. Applicants note that this document is cited on pages 207 and 210 of the specification of the present application;

European Patent Publication No. EP 1 352 650, together with family member WO 02/49632 and U.S. Patent Publication No. 2004/2569877 A1. Applicants note that the International Patent Publication is cited on page 6 of the specification of the present application;

MACIELAG, et al., "The Journal of Medicinal Chemistry," 1998, Vol. 41, No.16 page 2939-2945, Applicants note that this document is cited on page 102 of the specification of the present application;

WAISSER, et al., "Archiv der Pharmazie," 1998, Vol. 331, No.1, page 3-6, Applicants note that this document is cited on page 102 of the specification of the present application;

YAMAMOTO, et al., "Chemical and Pharmaceutical Bulletin," 1996, Vol. 44, page 734-745, Applicants note that this document is cited on page 121 of the specification of the present application;

HUNT, et al., "The Journal of the Chemical Society," 1956, page 3099-3107, Applicants note that this document is cited on page 127 of the specification of the present application;

ZWAAGSTRA, et al., "European Journal of Medicinal Chemistry," 1996, Vol.31, page 861-874, Applicants note that this document is cited on page 164 of the specification of the present application;

SOUTH, et al., "The Journal of Heterocyclic Chemistry," 1991, Vol. 28, page 1017-1024, Applicants note that this document is cited on page 165 of the specification of the present application;

TAJIKA, "Yakugaku Zasshi: The Journal of the Pharmaceutical Society of Japan," 1961, Vol. 81, page 1456-1459, together with partial English language translation of the same. Applicants note that this document is cited on page 167 of the specification of the present application;

OKAMIYA, "Nihon Kagaku Zasshi", 1962, Vol. 83, page 209-211, together with partial English language translation of the same. Applicants note that this document is cited on page 176 of the specification of the present application;

YURA, "Chemical and Pharmaceutical Bulletin," 1962, Vol.10, page 376-382, Applicants note that this document is cited on page 176 of the specification of the present application;

DIEZ-BARRA, et al., "Tetrahedron," 1997, Vol. 53, No. 33, page 11437-11448, Applicants note that this document is cited on page 180 of the specification of the present application;

SHARANIN, et al., "Zhournal Organicheskoi Khimii: Russian The Journal of Organic Chemistry," 1980, Vol.16, page 2185-2188, together with partial English language translation and Chemical Abstracts. Applicants note that this document is cited on page 185 of the specification of the present application;

HILL, et al., "Cell," 1993, Vol. 73, No. 2, page 395-406, Applicants note that this document is cited on page 199 of the specification of the present application;

European Patent Publication No. EP 0 221 211, together with family member Japanese Laid-open Patent Publication No. SHO 62-99329 and U.S. family members 4,560,549, 4,725,590 and U.S. 4,742,083. Applicants note that both documents are cited on pages 207 and 210 of the specification of the present application;

European Patent Publication No. EP 1 219 596, together with family member WO 01/12588, together with an English language Abstract and U.S. family member U.S. Patent No. 6,566,394;

Japanese Laid-open Patent Publication No. HEI 4-217916, together with an English language Abstract of the same;

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OHSUGI, et al., "Yakugaku Zasshi," 1976, Vol. 96, No. 2, page 165-169, together with an English language abstract of the same;

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European Patent Publication No. EP 0 317 991, together with family member Japanese Laid-open Patent Publication No. HEI 2-138260, together with an English language Abstract and U.S. family members U.S. Patent Nos. 4,786,644; 4,952,588 and 4,966,906;

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WO 99/24404, together with family member Japanese Laid-open Patent Publication No. 2001-522834, and U.S. family member U.S. Patent No. 6,022,884.

The Examiner's attention is also directed the following information, which includes commonly assigned U.S. applications:

- U.S. Application No. 10/433,619, to MUTO et al., which published as US2004/0259877 A1 and is cited above;
- U.S. Application No. 10/515,341, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07131, filed June 5, 2003, which published as WO 03/103648 A1 on December 18, 2003;

- U.S. Application No. 10/515,343, to MUTO et al., now published as US2006/0019958 A1, which is the U.S. National Stage of PCT/JP03/07130, filed June 5, 2003, which published as WO 03/103658 A1 on December 18, 2003;
- U.S. Application No. 10/515,623, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07120, filed June 5, 2003, which published as WO 03/103665 A1 on December 18, 2003;
- U.S. Application No. 10/515,342, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07129, filed June 5, 2003, which published as WO 03/103647 A1 on December 18, 2003;
- U.S. Application No. 10/515,622, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07127, filed June 5, 2003, which published as WO 03/103656 A1 on December 18, 2003;
- U.S. Application No. 10/516,292, to MUTO et al., now published as US2006/0014811 A1, which is the U.S. National Stage of PCT/JP03/07121, filed June 5, 2003, which published as WO 03/103655 A1 on December 18, 2003;
- U.S. Application No. 10/516,293, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07128, filed June 5, 2003, which published as WO 03/103657 A1 on December 18, 2003;

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254-258;
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      XU, et al., "The Journal of Neuroscience," 2001, Vol. 21, No.1, RC118, 5
pages;
      YAMAMOTO, et al., "The Journal of Clinical Investigation," 2001, Vol. 107,
No. 2, page 135-142;
      YIN, et al., "Cell," 1998, Vol. 93, No. 5, page 875-884;
      YUAN, et al., "Science," 2001, Volume 293, page 1673-1677;
      WO 93/24115;
      WO 96/17832:
      WO 98/20864;
      WO 99/46267, together with family member Japanese Patent Publication
No. 2002-506072 and U.S. family members:
      U.S. Patent No. 6,225,329;
      U.S. Patent No. 6,262,044;
      U.S. Patent No. 6,410,586;
      U.S. Patent Publication No. 2002/002199 A1;
      U.S. Patent Publication No. 2002/019412 A1;
      U.S. Patent Publication No. 2002/165398 A1;
      U.S. Patent Publication No. 2003/069267 A1;
      WO 99/55663 together with U.S. family members U.S. Patent No.
6,653,309 and U.S. Patent Publication No. 2004/087650 A1;
      WO 00/03991;
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WO 01/98290 together with Japanese family member JP2004-501146 and family member U.S. Patent No. 6,414,013;

European Patent Publication No. EP 0 221 346, together with family member Japanese Laid-open Patent Publication No. SHO 62-81359, together with an English language Abstract of the same and U.S. family member U.S. Patent No. 4,939,133;

European Patent Publication No. EP 0 452 873, together with family member Japanese Laid-open Patent Publication No. HEI 4-217981 and U.S. family member U.S. Patent No. 5,126,341;

European Patent Publication No. EP 0 483 881;

European Patent Publication No. EP 0 551 849, together with family member Japanese Laid-open Patent Publication No. HEI 6-9476 and U.S. family members U.S. Patent Nos. 5,589,514; 5,776,977 and 6,159,988;

European Patent Publication No. EP 1 088 819, together with family member Japanese Patent Publication No. 2001-114768 and U.S. family members U.S. Patent No. 6,787,652 and U.S. Patent Publication No. 2004/157844 A1;

Japanese Patent Publication No. 2000-80041 together with an English language Abstract of the same;

Japanese Patent Publication No. HEI 9-169747, together with an English language Abstract of the same;

Japanese Patent Publication No. SHO 63-104912, together with an English language Abstract of the same;

Japanese Patent Publication No. HEI 11-21243, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. HEI 11-217361, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. HEI 8-175990, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. 2000-169479, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. 52-110835, together with an English language Abstract of the same;

United Kingdom Patent Publication No. GB 1 099 865, together with family member French Patent Publication No. FR 1 481 713;

United Kingdom Patent Publication No. GB 2 031 410;

U.S. Patent No. 3,906,023;

U.S. Patent No. 4,358,443; and

U.S. Patent No. 4,661,630.

Further to 37 C.F.R. §1.98, copies of the U.S. patents and the co-pending U.S. applications are not enclosed. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Applicants respectfully request that the Examiner consider the above material and cite the same. Copies of the above-noted foreign documents and articles are attached hereto and all of the documents are listed on the attached PTO-1449 Form. The Examiner is requested to initial the appropriate spaces on the attached Form and to return a copy of the initialed Form to Applicants with the next official communication in the present application.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted material. However, if any fee is necessary for

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consideration of this Information Disclosure Statement, the undersigned hereby authorizes the charging of any fee necessary for the consideration of this statement, including any payment under 37 C.F.R. §1.17 (p), to Deposit Account No. 19-0089.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted, Susumu MUTO et al.

Bruce H. Bernstein Reg. No. 29,027

February 16, 2006 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191

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P26316.P27.doc Sheet 2 of 8 FORM PTO-1449 U.S. Department of Commerce Atty. Docket No. Application No. Patent and Trademark Office P26316 10/515,294 Applicant INFORMATION DISCLOSURE STATEMENT Susumu MUTO et al. BY APPLICANT (Use several sheets if necessary) Filing Date Group June 5, 2003 Not Yet Assigned **U.S. PATENT DOCUMENTS EXAMIN** ER FILING DATE INITIAL DATE NAME **CLASS** DOCUMENT NUMBER SUBCLASS IF APPROPRIATE DOW et al. 09/07/04 6 7 8 7 2 6 5 2004 / 0 1 08/12/04 5 7 4 4 DOW et al. 8 6 2 2 5 3 2 9 05/01/01 RICHTER et al. 6 2 6 2 0 4 4 07/17/01 MØLLER et al. 6 4 1 0 5 8 6 06/25/02 MOLLER et al. 2002 / 0 0 0 2 1 9 9 01/03/02 JEPPESEN et al. 2 2002 / 0 0 1 9 4 1 02/14/02 ANDRESEN et al. 1 5 3 9 8 11/07/02 2002 / 0 6 JEPPESEN et al. 2003 / 0 6 2 6 7 04/10/03 MOLLER et al. 2004 0 2 5 9 7 7 12/23/04 MUTO et al. 8 2006 9 8 12/26/06 MUTO et al. 0 1 9 5 **FOREIGN PATENT DOCUMENTS** TRANSLATION DOCUMENT NUMBER DATE COUNTRY **SUBCLASS** CLASS YES NO 1 8 1 9 04/04/01 E.P.O 8 8 2001 7 8 01/24/01 **JAPAN** 1 1 4 6 2000 8 0 0 4 1 03/21/00 **JAPAN** 9 7 7 06/03/97 **JAPAN** 1 9 4 6 2 0 4 9 1 05/10/88 63 **JAPAN** 99 / 2 6 7 09/16/99 W.I.P.O 4 6 7 2002 5 0 6 0 2 02/26/02 **JAPAN** 3 0 2 1 2 4 01/26/99 **JAPAN** 11 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) 12 OKAMIYA, "Nihon Kagaku Zasshi," 1962, Vol. 83, page 209-211, together with partial English language translation of the same. 13 YURA, et al., "Chemical and Pharmaceutical Bulletin," 1962, Vol.10, page 376-382. 14 DIEZ-BARRA, et al., "Tetrahedron," 1997, Vol. 53, No. 33, page 11437-11448. 15 DJURIC, et al., "The Journal of Medicinal Chemistry," 2000, Vol.43, No.16, page 2975-2981. 16 English language Abstract of JP 2000-80041. 17 English language Abstract of JP 9-169747. 18 English language Abstract of JP 63-104912.

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE CONSIDERED

English language Abstract of JP 11-21243.

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EXAMINER

FORM PTO-1449 U.S. Department of Commerce P26316 INFORMATION DISCLOSURE STATEMENT Atty. Docket No. P26316 Applicant										No.		Applica 10/515,	tion No. 294				
11	NFORM	ATIC				SUF CAN		TA	FEMENT		Applicant Susumu		TO et al.				
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U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. P26316

Application No. 10/515,294

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) Applicant Susumu MUTO et al.

Filing Date June 5, 2003 Group Not Yet Assigned

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P26316.P27.doc FORM PTO-1449 U.S. Department of Commerce Atty. Docket No. Application No. Patent and Trademark Office P26316 10/515,294 **Applicant** INFORMATION DISCLOSURE STATEMENT Susumu MUTO et al. BY APPLICANT (Use several sheets if necessary) Filing Date Group June 5, 2003 Not Yet Assigned **U.S. PATENT DOCUMENTS EXAMINER** FILING DATE INITIAL **DOCUMENT NUMBER** DATE NAME **CLASS SUBCLASS** IF APPROPRIATE 06/30/92 SUZUKI et al. 12/31/96 NAIK et al. 07/07/98 NAIK et al. 12/12/00 NAIK et al. 08/28/90 GLAMKOWSKI et al. GLAMKOWSKI et al. 10/30/90 **FOREIGN PATENT DOCUMENTS** CLAS TRANSLATION DOCUMENT NUMBER DATE COUNTRY **SUBCLASS** YES NO E.P.O 05/15/02 02/15/01 W.I.P.O 07/03/02 E.P.O 02/22/01 W.I.P.O 02/17/98 **JAPAN** 02/09/97 **JAPAN** 09/06/89 **JAPAN** 08/10/99 **JAPAN** 07/09/96 **JAPAN** 08/07/92 **JAPAN** 02/09/87 _ **JAPAN** 06/20/00 **JAPAN** 09/17/77 **JAPAN** _ 04/23/80 UNITED KINGDOM 07/15/69 UNITED KINGDOM 06/01/66 **FRANCE** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) English language Abstract of JP 8-175990. English language Abstract of JP 4-217916.

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